K040298

MAR 1 5 2004

SECTION 10 - 510(k) SUMMARY

Date of Application:	January 30, 2004

Applicant's and Manufacturer Name and Street Address:

ACIST Medical Systems, Inc.
7450 Flying Cloud Drive
Suite 150
Eden Prairie, MN 55344

Name of Contact Person:

Carl M. Beaurline
Vice President, Quality Assurance / Regulatory Affairs

Telephone and Fax Number of Contact Person:

Telephone: (952) 995-9319
Fax: (952) 995-9396

Proprietary Name:	ACIST Angiographic Injection System Contrast Management Disposable Kits
Common Name:	Angiographic Contrast Management System
Classification Number & Name:	21 CFR 880.5440, Intravascular Administration Set
Class:	Class II
Classification Panel:	CV
Product Code:	FPA

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Predicate Device(s):

B2000, Automated Manifold Kit (w/o Transducer)
BT2000, Automated Manifold Kit (w/Transducer)
H1000, AngioTouch Hand Controller
EH2000, AngioTouch Hand Controller
H1000P, AngioTouch Hand Controller
EH2000P, AngioTouch Hand Controller
H1000IJ, AngioTouch Hand Controller
H1000J, AngioTouch Hand Controller

Device Intended Use:

The ACIST Medical Systems Angiographic Injection System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.

Device Description:

The ACIST Medical Systems Angiographic Injection System Contrast Management Disposable Kits provide the interface between the ACIST Injection System and the Angiographic patient catheter for the delivery of contrast media at a user-determined variable flow rate that can be instantaneously and continuously varied.

The Contrast Management Disposable Kits are comprised of the following elements:

- Automated Manifold
- AngioTouch Hand Controller
- Reusable Syringe Kit *

* Not affected by this change, but provided with the Contrast Management Disposable Kits is the Reusable Syring Kit.

Summary of Comparative Technological Characteristics with Predicate Device:

- There are no differences in technological characteristics with respect to the predicate device.

Summary of Non-Clinical Performance Data for Determination of Substantial Equivalence with Predicate Device:

- Non-clinical performance testing was not indicated for determination of substantial equivalence.

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Summary of Clinical Performance Data for Determination of Substantial Equivalence with Predicate Device:

- Clinical performance testing was not indicated for determination of substantial equivalence.

Summary of Conclusions Drawn from Non-Clinical & Clinical Tests:

- Non-clinical and clinical testing was not performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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ACIST Medical Systems, Inc.
c/o Mr. Carl M. Beaurline
Vice President, Quality Assurance/Regulatory Affairs
7450 Flying Cloud Drive, Suite 150
Eden Prairie, MN 55344

Re: K040298
Trade/Device Name: ACIST Angiographic Injection System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: DXT
Dated: March 4, 2004
Received: March 9, 2004

Dear Mr. Beaurline:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K040298

Device Name: ACIST Angiographic Injection System

Indications for Use:

The ACIST Angiographic Injection System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

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